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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/016,850
Filing Date: December 14, 2001
Appellant(s): HUGHES ET AL.

Carlos Fisher
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 13, 2006 appealing from the Office action mailed July 13, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2001/0047012	Desantis, JR.	11-2001
WO01/92288	Collins et al.	12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 9, 11-12, 14-16 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desantis, JR. (US 2001/0047012) and Collins et al. (WO 01/92288).

Desantis teaches a combination therapy for treating glaucoma using a glutamate antagonist and an intraocular pressure-lowering compound. Brimonidine is taught as the preferred intraocular pressure-lowering compound, and memantine is considered a glutamate antagonist being added to brimonidine. See claims 1-7. Collins teaches various pharmaceutical conjugates comprising a bioactive agent that is covalently bound directly or indirectly to a linker. Efficacy enhancing components of formula A are disclosed on page 92. Therefore, in view of the combined teachings of Desantis and Collins, one skilled in the art of formulation chemistry who seeks a pharmaceutical conjugate comprising a therapeutic component and an efficacy enhancing component of instant formula A would have been motivated to prepare a formulation comprising two known therapeutically effective ophthalmic agents in a formulation that is conjugate to treat ocular pathologies. Such would have been obvious in the absence of evidence to the contrary, because memantine is established in the prior art as useful agent for conjugation with poorly soluble drugs. Such conjugates provide chemical stability and are known to dissociate under physiological conditions. The intended uses, as defined in claim 1 as "a therapeutic component" and "an efficacy enhancing component" confer no patentable weight to the composition claims. The applied references teach the combination of a compound of instant formula A with various therapeutic agents. The specification fails to define a "conjugate" as anything more than the combination of compounds wherein increased solubility or bioavailability is sought.

(10) Response to Argument

Appellant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Appellant in his arguments refer to a declaration filed at the same time as the Appeal Brief, trying to establish that the claimed prodrug conjugates selectively targeted to melanin, which is preferentially found in the retinal epithelium of the posterior of the eye. Appellant is informed that the declaration is not considered for the reasons set forth in MPEP 1206 and 37 CFR 41.33 (c) (2). Appellant also alleges criticality to the differences in function of the claimed combination and the combination of the prior art. Appellant is reminded that the claims of the instant application are composition claims, therefore the intended use confer no patentable weight to the composition claims. In conclusion, Desantis teaches a combination of brimonidine and memantine (elected species by appellant) in an ophthalmic formulation for the treatment of glaucoma. Collins et al. teach pharmaceutical conjugates with ophthalmic application. Efficacy enhancing components of Formula A are disclosed on page 92. The applied references teach the combination of compounds of formula A, such as memantine in combination with therapeutic agents such as brimonidine. The specification fails to define a "conjugate" as anything more than the combination of compounds wherein the increased solubility or bioavailability is sought.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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